

Proposed revision of the current BSE chapter

The Bureau took Member Countries comments into account in revising the current BSE chapter.

In the absence of new scientific information on the risks presented, Article 2.3.13.1 was not modified with respect to specific commodities. This approach on tallow reflects the position of the BSE *ad hoc* Group. The Bureau understands that the results of an investigation into whether or not the BSE agent may be present in tallow will soon be released. In addition, while the *ad hoc* Group believed that the information available indicated that 'bovine blood and blood by-products' would be safe (subject to stunning being carried out in accordance with Article 2.3.13.14), the Bureau awaits further concrete scientific information before making recommendations on their use.

Article 2.3.13.2 was modified, taking into consideration the recommendations of the *ad hoc* Group on the factors important to release and exposure assessments.

Revised text submitted by the EU and Canada on Article 2.3.13.3 (and on Articles 2.3.13.4, 2.3.13.5, 2.3.13.12 and 2.3.13.16 for Canada) was not adopted as it was not considered to significantly improve the existing risk mitigation.

A comment from Australia and Canada regarding the age cut-off in Articles 2.3.13.5 and 2.3.13.6 was not adopted as the *ad hoc* Group believed that an age of 24 months was the usual cut off point for animal census data; if the ages were aligned at 24 months, the *ad hoc* Group considered that the prevalence cut-off limits for the categories would need to be adjusted.

The wording of paragraph 2) c) of Article 2.3.13.6 was clarified.

On the recommendation of the *ad hoc* Group and in light of comments from Canada, recommendations for post-mortem inspection were added to Articles 2.3.13.13, 2.3.13.14, 2.3.13.15 and 2.3.13.20 to address the need to certify to certain tissues having been removed in a manner to avoid contamination.

A Japanese recommendation that meat-and-bone meal be banned even from BSE-free countries was not adopted as it was considered to be excessive for exporting countries not affected by BSE.

The age cut-off for mechanically separated meat from skull and vertebral column in Article 2.3.13.16 was changed from 6 to 12 months on the recommendation of the *ad hoc* Group and for consistency with Article 2.3.13.18.

The current recommendation to remove the entire intestine was reconsidered by the Bureau, and in view of comments from the USA, Thailand, Taiwan, Korea, Canada and Japan and advice from an expert, the Bureau now proposes that Article 2.3.13.18 be modified to require the exclusion from trade of the distal ileum only.

The Bureau considered that the recommendations in Article 2.3.13.22 are substantially incorporated into Article 2.3.13.2 and proposes deletion of this Article.

The proposed modifications are submitted to Member Countries for comment.

PROPOSED MODIFIED CHAPTER

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

- 1) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE status of the cattle population of the exporting country or zone/compartment:
 - a) *milk* and *milk products*;
 - b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
 - c) hides and skins (excluding hides and skins from the head);
 - d) gelatin and collagen prepared exclusively from hides and skins (excluding hides and skins from the head);
 - e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;
 - f) dicalcium phosphate (with no trace of protein or fat).
- 2) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE status of the cattle population of the exporting country or zone/compartment:
 - a) cattle;
 - b) *fresh meat* and *meat products*;
 - c) gelatin and collagen prepared from bones or from hides and skins from the head;
 - d) tallow and tallow derivatives, other than protein-free tallow as defined above;
 - e) dicalcium phosphate, other than dicalcium phosphate with no trace of protein or fat.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.3.13.2.

The BSE risk status of the cattle population of a country or zone/compartment can only be determined on the basis of the following criteria:

- 1) the outcome of a risk assessment (which is reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic

perspective:

a) Release assessment

Release assessment consists of assessing the likelihood that a transmissible spongiform encephalopathy (TSE) agent has been introduced into the cattle population from a pre-existing TSE in the indigenous ruminant population or via the ~~importation of the~~ following commodities potentially contaminated with a TSE agent:

- i)a) meat-and-bone meal or greaves from the indigenous ruminant population;
- i)b) imported meat-and-bone meal or greaves;
- ii) imported live animals;
- iii) imported animal feed and feed ingredients;
- iv) imported products of ruminant animal origin for human consumption, which may have contained tissues listed in Article 2.3.13.18 and may have been fed to cattle;
- v) imported products of ruminant origin for *in vivo* use in cattle.

b) Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle susceptible animal species, through a consideration of the following:

- i)a) ~~epidemiological situation concerning all the presence or absence of~~ animal TSE agents in the country or zone/compartiment and, if present, their prevalence based on the outcomes of surveillance;
 - i)b) prevalence of infection of animals with TSE agents in the country or zone/compartiment, including the surveillance and other epidemiological investigations on which the determination is based;
 - ii) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal or greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
 - iii) ~~the origin and~~ use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
 - iv) ~~implementation and enforcement of feed bans, the feeding or not of ruminants with~~ *meat-and-bone meal and greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;
- 2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases showing

clinical signs consistent with BSE in target sub-populations as defined in Articles 3.8.4.2 and 3.8.4.3 of neurological disease in adult cattle as well as fallen stock;

- 3) compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;
- 4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4.; records of the number and results of investigations should be maintained for at least 7 years;
- 5) examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

Article 2.3.13.3.

BSE free country or zone/compartiment

The cattle population of a country or zone/compartiment may be considered free of BSE, should the following conditions be met:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and either:
 - a) there has been no *case* of BSE; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or
 - ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* has been fed to ruminants;

OR

- b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and ~~the affected cattle~~ all BSE cases as well as, if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone/compartiment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or
 - ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* has been fed to ruminants;

OR

- c) the last indigenous *case* of BSE was reported more than 7 years ago, and
- i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; and
 - ii) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced for at least 8 years; and
 - iii) ~~the affected cattle as well as:~~
 - ~~if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and~~
 - ~~all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified and their movements controlled, and when slaughtered or at death, are completely destroyed, or~~
 - ~~where the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, are permanently identified and their movements controlled, and when slaughtered or at death, are completely destroyed.~~
 - iii) all BSE cases, as well as:
 - = all the progeny of female cases, born within 2 years prior to or after clinical onset of the disease, and
 - = all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
 - = if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE cases,

if alive in the country or zone/compartiment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

Article 2.3.13.4.

BSE provisionally free country or zone/compartiment

The cattle population of a country or zone/compartiment may be considered as provisionally free of BSE, should the following conditions be met:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and either:

- a) there has been no *case* of BSE; and either:
- i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or
 - ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years;

OR

- b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and ~~the affected cattle~~ all cases of BSE as well as, if these are females, all their progeny born within 2 years prior to or after clinical onset of the disease, if alive in the country or zone/compartiment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed; and either:
- i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or
 - ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years.

Article 2.3.13.5.

Country or zone/compartiment with a minimal BSE risk

The cattle population of a country or zone/compartiment may be considered as presenting a minimal BSE risk, should the country or zone/compartiment comply with the following requirements:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and

EITHER:

- a) the last indigenous *case* of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.2. are complied with and the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants is effectively enforced, but:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have not been complied with for 7 years; or
 - ii) the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has not been effectively enforced for 8 years;

OR

b) the last indigenous *case* of BSE has been reported less than 7 years ago, and the BSE incidence rate, calculated on the basis of indigenous *cases*, has been less than two *cases* per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age in the country or zone/compartiment (*Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.*), and:

i) the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced for at least 8 years;

ii) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years;

~~iii) the affected cattle as well as:~~

- ~~- if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and~~
- ~~- all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, or~~
- ~~- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.~~

iii) all BSE *cases*, as well as:

- = all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and
- = all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- = if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country or zone/compartiment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

Article 2.3.13.6.

Country or zone/compartiment with a moderate BSE risk

The cattle population of a country or zone/compartiment may be considered as presenting a moderate BSE risk if:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted, and the other criteria listed in Article 2.3.13.2. are complied with;
- 2) the BSE incidence rate has been measured using a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4., and is:

- a) if based only on Article 3.8.4.2., greater than or equal to, one indigenous *case* per million and less than or equal to, one hundred indigenous *cases* per million within the cattle population over 24 months of age in the country or zone/compartiment calculated over the past 12 months; or
- b) if based on Articles 3.8.4.2., 3.8.4.3. and 3.8.4.4., greater than, or equal to, two indigenous *cases* per million and less than, or equal to, two hundred indigenous *cases* per million within the cattle population over 24 months of age in the country or zone/compartiment calculated over the past 12 months; or
- c) less than two indigenous *cases* per million per year, but for less than the four consecutive 12-month periods required in paragraph 2) b) of Article 2.3.13.5 (*Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.*);

~~3) the affected cattle as well as:~~

- ~~a) if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and~~
- ~~b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, or~~
- ~~e) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.~~

3) all BSE cases, as well as:

- a) all the progeny of female cases, born within 2 years prior to or after clinical onset of the disease, and
- b) all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and

within 12 months of the birth of, the BSE cases,

if alive in the country or zone/compartiment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

Countries and zones/compartiments where the BSE incidence rate has been less than one indigenous case per million within the cattle population over 24 months of age during each of the last four consecutive 12-month periods, but where at least one of the other requirements to be considered as provisionally free from BSE or as presenting a minimal BSE risk is not complied with, shall be considered as countries or zones/compartiments with a moderate BSE risk.

Article 2.3.13.7.

Country or zone/compartiment with a high BSE risk

The cattle population of a country or zone/compartiment may be considered as presenting a high BSE risk if it cannot demonstrate that it meets the requirements of another category.

Article 2.3.13.8.

When importing from a BSE free country or zone/compartiment, *Veterinary Administrations* should require:

for all commodities from cattle not listed in point 1) of Article 2.3.13.1.

the presentation of an *international veterinary certificate* attesting that the country or zone/compartiment complies with the conditions in Article 2.3.13.3. to be considered as free of BSE.

Article 2.3.13.9.

When importing from a BSE provisionally free country or zone/compartiment, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone/compartiment complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;
- 2) cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females.

Article 2.3.13.10.

When importing from a country or zone/compartiment with a minimal BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone/compartiment complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;
- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

- 3) cattle selected for export:
 - a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not exposed cattle as described in point 2) b) iii) of Article 2.3.13.5.;
 - b) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced.

Article 2.3.13.11.

When importing from a country or zone/compartiment with a moderate BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone/compartiment complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;
- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 3) cattle selected for export:
 - a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not exposed cattle as described in point 3) of Article 2.3.13.6.;
 - b) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced.

Article 2.3.13.12.

When importing from a country or zone/compartiment with a high BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone/compartiment complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;
- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 3) ~~all affected cattle as well as:~~
 - a) ~~if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and~~

- b) ~~all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or~~
- e) ~~if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle,~~

~~if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed;~~

3) all BSE cases, as well as:

- a) all the progeny of female cases, born within 2 years prior to or after clinical onset of the disease, and
- b) all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE cases,

if alive in the country or zone/compartiment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed;

4) cattle selected for export:

- a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;
- b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 2.3.13.13.

When importing from a BSE provisionally free country or zone/compartiment, *Veterinary Administrations* should require:

for fresh meat (bone-in or deboned) and meat products from cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone/compartiment complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;
- 2) ante-mortem ~~inspection is~~ and post-mortem inspections were carried out on all cattle from which the fresh meat or meat products destined for export originate.

Article 2.3.13.14.

When importing from a country or zone/compartiment with a minimal BSE risk, *Veterinary Administrations* should require:

for fresh meat (bone-in or deboned) and meat products from cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone/compartiment complies with the conditions in Article 2.3.13.5. to be

considered as presenting a minimal BSE risk;

- 2) ~~ante-mortem inspection is~~ and post-mortem inspections were carried out on all cattle from which the fresh meat or meat products destined for export originate;
- 3) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);
- 4) the *fresh meat* and *meat products* destined for export do not contain the tissues listed in point 3) of Article 2.3.13.18., nor mechanically separated meat from skull and vertebral column from cattle over 30 months of age, all of which have been completely removed in a manner to avoid contamination with these tissues.

Article 2.3.13.15.

When importing from a country or zone/compartiment with a moderate BSE risk, *Veterinary Administrations* should require:

for fresh meat (bone-in or deboned) and meat products from cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone/compartiment complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;
- 2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 3) ~~ante-mortem inspection is carried out on all bovines;~~ ante-mortem and post-mortem inspections were carried out on all cattle from which the fresh meat or *meat products* originate;
- 4) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;
- 5) the *fresh meat* and *meat products* destined for export do not contain the tissues listed in point 1) and point 2) of Article 2.3.13.18. nor mechanically separated meat from skull and vertebral column from cattle over 6 12 months of age, all of which have been completely removed in a manner to avoid contamination with these tissues.

Article 2.3.13.16.

When importing from a country or zone/compartiment with a high BSE risk, *Veterinary Administrations* should require:

for fresh meat and meat products from cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country or zone/compartiment complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;

- 2) the meat destined for export does not contain the tissues listed in point 1) of Article 2.3.13.18., all of which have been completely removed in a manner to avoid contamination with these tissues;
- 3) the meat destined for export, if obtained from animals over 9 months of age, has been deboned and does not contain nervous and lymphatic tissues exposed during a deboning process, all of which have been completely removed in a manner to avoid contamination with these tissues;
- 4) the *meat products* destined for export are derived from deboned meat and do not contain the tissues listed in point 1) and point 2) of Article 2.3.13.18. nor nervous and lymphatic tissues exposed during a deboning process, nor mechanically separated meat from skull and vertebral column of bovine animals, all of which have been completely removed in a manner to avoid contamination with these tissues;
- 5) a system is in operation enabling the *fresh meat* and *meat products* destined for export to be traced back to the *establishments* from which they are derived;
- 6) ante-mortem inspection is carried out on all bovines;
- 7) the cattle from which the *meat* or *meat products* destined for export originate:
 - a) were identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;
 - b) are not the progeny of BSE suspect or confirmed females; and either:
 - i) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced; or
 - ii) were born, raised and had remained in herds in which no *case* of BSE had been confirmed for at least 7 years;
 - c) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;
- 8) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 9) ~~all affected cattle as well as:~~
 - a) ~~if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and~~
 - b) ~~all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, or~~
 - c) ~~if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death,~~

~~are completely destroyed.~~

2) all BSE cases, as well as:

- a) all the progeny of female cases, born within 2 years prior to or after clinical onset of the disease, and
- b) all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE cases,

if alive in the country or zone/compartiment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed;

Article 2.3.13.17.

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from countries with a minimal, moderate or high BSE risk should not be traded between countries.

Article 2.3.13.18.

- 1) From cattle of any age originating from a country or zone/compartiment with a moderate or a high BSE risk, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum intestine, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.
- 2) From cattle originating from a country or zone/compartiment with a moderate or a high BSE risk, that were at the time of slaughter over 12 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.
- 3) From cattle, originating from a country or zone/compartiment with a minimal BSE risk, that were at the time of slaughter over 30 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes and spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 2.3.13.19.

Veterinary Administrations of importing countries should require:

for gelatin and collagen prepared from bones or from hides and skins from the head and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the ~~bones~~ commodities came from:

- 1) a BSE free or provisionally free country or zone/compartiment, or from a country or zone/compartiment with a minimal BSE risk; or
- 2) a country or zone/compartiment with a moderate BSE risk; and
 - a) skulls and vertebrae (excluding tail vertebrae, and from hides and skins from the head) have been excluded;
 - b) the bones have been subjected to a process which includes all the following steps:
 - i) pressure washing (degreasing),
 - ii) acid demineralisation,
 - iii) prolonged alkaline treatment,
 - iv) filtration,
 - v) sterilisation at $\geq 138^{\circ}\text{C}$ for a minimum of 4 seconds,or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.20.

Veterinary Administrations of importing countries should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

- 1) a BSE free or provisionally free country or zone/compartiment, or
- 2) a country or zone/compartiment with a minimal BSE risk, and it originates from cattle which have been subjected to ~~an~~ ante-mortem and post-mortem inspections for BSE with favourable results and has not been prepared using the tissues listed in point 3 of Article 2.3.13.18., or
- 3) a country or zone/compartiment with a moderate BSE risk, and it originates from cattle which have been subjected to ~~an~~ ante-mortem and post-mortem inspections for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 2.3.13.18.

Article 2.3.13.21.

Veterinary Administrations of importing countries should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

- 1) they originate from a BSE free or provisionally free country or zone/compartiment, or from a country or zone/compartiment with a minimal BSE risk;

OR

- 2) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

~~Article 2.3.13.23.~~

~~Careful selection of source materials is the best way to ensure maximum safety of ingredients or reagents of bovine origin used in the manufacture of medicinal products.~~

~~Countries wishing to import bovine materials for such purposes should therefore consider the following factors:~~

- ~~1) the BSE status of the country and herd(s) where the animals have been kept, as determined under the provisions of Articles 2.3.13.2. to 2.3.13.7.;~~
- ~~2) the age of the donor animals;~~
- ~~3) the tissues required and whether or not they will be pooled samples or derived from a single animal.~~

~~Additional factors may be considered in assessing the risk from BSE, including:~~

- ~~4) precautions to avoid contamination during collection of tissues;~~
- ~~5) the process to which the material will be subjected during manufacture;~~
- ~~6) the amount of material to be administered;~~
- ~~7) the route of administration.~~